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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,867	04/16/2004	Jason W. Chin	54-000240US	8312

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EXAMINER	
GEBREYESUS, KAGNEW H	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,867	CHIN ET AL.	
	Examiner	Art Unit	
	Kagnew H. Gebreyesus	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-138* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-138* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-37, 58, 59, 61-65, 117 are drawn to a eukaryotic cell comprising an orthogonal tRNA synthetase (ORS) as set forth in SEQ ID NO: 36-47 or 86, classified in class 435, subclass 325.

II. Claims 61-65 are drawn to a nucleic acids, vectors comprising the same and cell comprising the vector encoding an O-RS or a complementary polynucleotide or a conservative variant thereof classified in class 536, subclass 23.2

III. Claims 38-57, 131-133 are drawn to a composition comprising a protein in a eukaryotic cell, wherein the protein comprises at least one unnatural amino acid classified in class 530, subclass 350.

IV. Claim 60 are drawn to antibodies or sera specific to a polypeptide selected from the group consisting of a polypeptide that comprises an amino acid sequence as shown in SEQ ID NO: 36-47 or 86 and variants thereof classified in class subclass

V. Claims 66-116, 118, 119 are drawn to a method of producing an orthogonal aminoacyl-tRNA synthetase (O-RS) that preferentially aminoacylates an orthogonal tRNA with an unnatural amino acid in a eukaryotic cell by a positive and negative selection process classified in class 435 subclass 29.

VI. Claims 120-129, 134 and 135 are drawn to a method of producing in a eukaryotic cell at least one protein that comprises at least one unnatural amino acid

comprising an ORS of SEQ ID NO: 36-48 or 86 and an OtRNA of SEQ ID NO: 64 or 65 and the protein produced 435, subclass 455.

VII. Claims 136-138 are drawn to a kit for producing a protein that comprises at least one unnatural amino acid in a cell, the kit comprising: a container containing a polynucleotide sequence encoding an O-tRNA, and a polynucleotide sequence encoding an O-RS or an O-RS and an instructional material classified in class 435 subclass 41.

Groups I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, Group I has a separate utility, such as in the production of antibodies to recognize orthogonal tRNA synthetases, and Group II has separate utility such as hybridization assays to identify similar orthogonal tRNAs. See M.P.E.P § 806.05(d). Thus, Groups I and II are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The ORS of invention I and the polypeptide of invention III comprising an unnatural amino acid are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as being capable of use together and they have different modes of operation, different function, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the ORS of group I are

separate and distinct from the polypeptide of group III as they are structurally and functionally distinct chemical entities. Accordingly restriction is appropriate.

Inventions I and IV are related because the ORS is used to produce the antibodies. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are not capable of use together and are not obvious variants of each other. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Groups I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the orthogonal tRNA synthetase can be made by genetic engineering using structural data to indicate appropriate modifications to produce the proper functional characteristics required by the claims. Thus, Groups I and V are patentably distinct. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group V based on the distinct method steps that must be searched in Group V, restriction for examination purposes as indicated is proper.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the ORS can be used to make the antibodies

Inventions I and VII are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, inventions I as claimed has a different function and effect. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions comprise nucleic acid sequences encoding an unrelated proteins.

The polynucleotide of Group II and the antibodies of group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as being capable of use together and they

have different modes of operation, different function, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide in group II are separate and distinct from the antibodies in group IV as they are physically and functionally distinct chemical entities. Accordingly restriction is appropriate.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acid sequences can be used as hybridization probes.

Inventions II and the inventions in VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acid sequences of II can be used as hybridization probes rather than in the process of making a protein comprising an unnatural amino acid or in the kit.

Inventions II and VII are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP §

806.05(j). In the instant case, inventions II as claimed is drawn to nucleic acids encoding the ORS thus as claimed has a different function and effect. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

The protein comprising an unnatural amino acid (polypeptide of interest) of Group III and the antibodies of group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as being capable of use together and they have different modes of operation, different function, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies in group IV is not made or used with the polypeptide of interest of Group III as they are physically and functionally distinct chemical entities. Accordingly restriction is appropriate.

Inventions III and V are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the product obtained by the invention of Group III is neither made or used by the invention of group V.

Groups III and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the polypeptide comprising an unnatural amino acid can be made by chemically synthesizing the polypeptide comprising the unnatural amino acid. Thus, Groups III and VI are patentably

distinct. Because these inventions are distinct for the reasons given above and the search required for Group VI is not necessarily required for Group III restriction for examination purposes as indicated is proper.

Inventions III and VII are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, inventions III as claimed is drawn to polypeptides comprising unnatural amino acids thus as claimed has a different function and effect. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions IV and V, VI, VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the antibody of invention IV cannot be used in the method of VI or in the method of VI or the kit of invention VII.

Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP

§ 806.05(h). In the instant case the protein having unnatural amino acid can be synthesized chemically.

Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the kit can be used in an in-vitro translation method given that it can contain the ORS polypeptide rather than the polynucleotide encoding the ORS.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43).

Applicant is reminded that upon the cancellation of claims to a none elected invention the none elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable,

withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kagnew Gebreyesus Ph.D.
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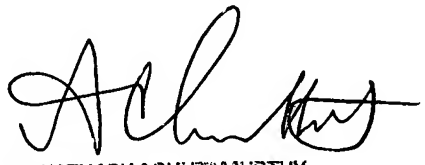

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